

Remarks

Applicants respectfully request that the Examiner reconsider the present application in view of the foregoing amendments and the following remarks.

The Office Action is non-final. Claims 1-24 are pending in the present application. Claims 3, 6 and 13 are withdrawn from further consideration as being directed to a non-elected invention. Claims 1 and 21 have been amended to further clarify and define the invention.

Support for claim 1 can be found on page 2, lines 10-13, and page 9, lines 9-10 of the present specification. Claim 21 has been amended to add “soluble” which was inadvertently removed from the claim in the Amendment dated August 7, 2008.

Entry of the present Amendment is respectfully requested.

Rejection Under 35 U.S.C § 112, Second Paragraph

Claims 1-2, 4-5, 7-12 and 14-24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Concerning claim 1, the Examiner indicates that the term “derivative” renders the claim indefinite.

Additionally, the Examiner asserts that claims 15, 16 and 24 recite the broad recitation “granules,” as well as reciting “fine granules,” which is the narrower statement of “granules.” The Examiner asserts that a narrow range or limitation that falls within the broad range or limitation is considered indefinite.

Concerning claim 21, it is unclear to the Examiner how a coating layer can be a “coating layer within a range of pH 6.0 to pH 7.5.”

Applicants respectfully traverse the rejection.

Applicants have amended claim 1 to recite “hydroxy propyl methyl cellulose,” thus resolving the issue as to claim 1. Further, Applicants have amended claim 21 to recite “wherein

the controlled-release coating layer is a coating layer soluble within a range of pH 6.0 to pH 7.5.”

Applicants inadvertently omitted “soluble “from the claim in a previous response.

Regarding the issue concerning claims 15, 16 and 24, Applicants respectfully disagree that these claims are indefinite.

Applicants submit that within the knowledge of the art, the term “granule” is not recognized as a broader concept of the term “fine granule.” Both terms are clearly distinguished from each other by their respective particle sizes.

To further emphasize the knowledge within the art, Applicants herein provide for the Examiner’s consideration, Exhibit 1 (“GENERAL RULES FOR PREPARATIONS,” The Japanese Pharmacopoeia Fifteenth Edition (JP XV)).

Applicants direct the Examiner’s attention to Exhibit 1, specifically, to the description of granules located on page 10, Section 9, “Granules.” Further, Applicants note the description of fine granules, located on page 14, Section 21, “Powders,” where powders have a fine particle size.

Based on the Exhibit and knowledge within the art, Applicants submit that claims 15, 16, and 24 are definite.

In view of the above, Applicants submit that the claims particularly point out and distinctly claim the subject matter the Applicants regard as the invention.

Applicants respectfully request reconsideration and withdrawal of the present rejection.

Rejection Under 35 U.S.C § 103(a)

Claims 1-2, 4-5, 7-12 and 14-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Patel *et al.*, U.S. Patent Application No. 2005/0181052 (hereinafter “Patel”) in view of Scott *et al.*, U.S. Patent No. 6,887,307 (hereinafter “Scott”).

Applicants respectfully traverse the rejection.

The Examiner's Position:

The Examiner asserts that the present application is obvious in light of the above cited references, as indicated on pages 4-7 of the outstanding Office Action.

Based on the following, Applicants contend that the Examiner's position is not supportable, thereby making the presently claimed invention unobvious over the Patel and Scott references.

Applicants' Position

The present application relates to a preparation obtained by using a capsule which is stable in a low moisture state and has pH-independent disintegration properties wherein the preparation comprises a medicine unstable to moisture.

According to the presently claimed invention, a preparation in which not only the medicine but also the capsule are stabilized, even if the medicine is unstable to moisture and the moisture content in the preparation is lowered, can be provided (see page 1, lines 3-7, and page 8, line 25 to page 10, line 1 of the present specification).

Differences between the Presently Claimed Invention and the Cited References

Patel

The Patel reference relates to a microtablet comprising lansoprazole and a lubricant and has an enteric coating, wherein the microtablet is free of a separating or intermediate layer between the medicine and the enteric coating, and is free of an alkaline reacting compound (see Patel, paragraphs [0010] and [0015]). Patel also discloses a hard gelatin capsule in Example 2 (see Patel, paragraph [0069]).

The Patel reference stabilizes a composition by adding a lubricant. Patel discloses a capsule as an example of the preparation (Example 2) and usable capsules (see Patel, paragraph [0063]).

However, the Patel reference describes only gelatin capsules. Patel does not describe pullulan capsules, as the Examiner has acknowledged.

Scott

The Scott reference relates to an improved pullulan capsule, and discloses that the addition of a hydrocolloid or a mixture of hydrocolloids as a setting system to a pullulan solution confers an appropriate setting ability with cooling to the pullulan solution, thereby hard pullulan capsules can be produced with a conventional dip moulding process (see Scott, column 2, line 64 to column 3, line 20).

The Scott reference states that "Higher product quality consistency," "low water content" and "high stability of various properties over storage" are among the advantages of pullulan (see Scott, column 3, line 66, to column 4, line 10).

However, Scott does not describe any medicine other than acetaminophen, which is described in Figure 1.

Also, the problem to be solved indicated in the Scott reference is to manufacture hard capsules having a certain level of hardness from pullulan using a conventional dip moulding process on equipment at an industrial scale (see Scott, column 2, line 63 to column 3, line 5; column 3, lines 14-20; column 3, lines 25-32; and column 4, lines 20-26).

Additionally, Scott also states that "Very low oxygen permeability. Its capsules are particularly useful for the filling of oxygen sensitive products" as an advantage of pullulan (see Scott, column 4, lines 6-7).

However, Scott does not describe any medicine unstable to moisture.

Applicants also note that Acetaminophen, which is the only disclosed medicine in the Scott reference, is stable to moisture. Applicants herein enclose Exhibit 2 (TYLENOL®

(acetaminophen) Product sheet) and Exhibit 3 (Rosenberg *et al.*, "Which Oral Solid Medications Should be Protected from Light and/or Moisture?") for the Examiner's consideration.

Obviousness has not been Established

As indicated in MPEP § 2143, the Examiner must resolve the factors described in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which provides the controlling framework for an obviousness analysis, before utilizing the rationales that were established in *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Applicants submit that based on the differences between the invention and the cited references, as well as the unexpected effects described above, the Examiner has not resolved the *Graham* factor of ascertaining the differences between the prior art and the claims that are at issue, and therefore the rationale the Examiner provides for the rejection is improper.

"When an applicant submits evidence, whether in the specification as originally filed or in reply to a rejection, the examiner must reconsider the patentability of the claimed invention. The decision on patentability must be made based upon consideration of all the evidence, including the evidence submitted by the examiner and the evidence submitted by the applicant. A decision to make or maintain a rejection in the face of all the evidence must show that it was based on the totality of the evidence. Facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion of obviousness was reached, not against the conclusion itself." In re Eli Lilly & Co., 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990). (See MPEP§ 2142; emphasis added)

Based on the above, Applicants submit that there is no teaching or motivation to combine the Patel reference (which describes lansoprazole as a medicine and only gelatin capsules as the capsule) with Scott (which does not describe the use of a medicine unstable to moisture), as the Examiner asserts.

Therefore, based on the above discussion, Applicants respectfully submit that impermissible hindsight reconstruction was used in support of the suggested combination of references relied upon by the Examiner. See MPEP § 2142.

In light of the above amended claims and remarks, Applicants submit that the assertions made by the Examiner regarding the Patel and Scott references are incorrect, thus making the Examiner's position not supportable. Accordingly, based on the differences between the presently claimed invention and the above references, the presently claimed invention is not obvious to one of ordinary skill in the art.

Regarding the secondary reference, Scott, it fails to remedy the deficiencies of the Patel reference. Therefore, even if the references were combined in the manner asserted by the Examiner, the result of such a combination would still not suggest the presently claimed invention.

Since claims 2, 4-5, 7-12 and 14-24 ultimately depend from amended claim 1, these claims are unobvious over the cited references for the same reasoning above.

Applicants respectfully request reconsideration and withdrawal of the above rejection.

Conclusion

Applicants respectfully submit that all of the rejections raised by the Examiner have been overcome, and that the present application now stands in condition for allowance.

Should there be any outstanding matters that need to be resolved, the Examiner is respectfully requested to contact Paul D. Pyla at the telephone number below, in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized to charge payment or credit any overpayment to Deposit Account No. 23-0975 for any additional fees required under 37 C.F.R. §§1.16 or 1.17.

Respectfully submitted,

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Attachments:

Exhibit 1: "GENERAL RULES FOR PREPARATIONS," The Japanese Pharmacopoeia Fifteenth Edition (JP XV).

Exhibit 2: TYLENOL® (acetaminophen) Product sheet (<http://www.rxlist.com/tylenol-drug.htm>)

Exhibit 3: Rosenberg *et al.*, "Which Oral Solid Medications Should be Protected from Light and/or Moisture?" (<http://drugtopics.modernmedicine.com/drugtopics/pharmacy/clinical-Q-and-A-Which-oral-solid-medications-should/articlestandard/Article/detail/515477>).

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Application No.: 10/591,164

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EXHIBIT 1

(12 pages total, including cover)

The Ministry of Health, Labour and Welfare Ministerial Notification No. 285

Pursuant to Paragraph 1, Article 41 of the Pharmaceutical Affairs Law (Law No. 145, 1960), the Japanese Pharmacopoeia (hereinafter referred to as "new Pharmacopoeia"), which has been established as follows*, shall be applied on April 1, 2006, and the Ministry of Health, Labour and Welfare Ministerial Notification No. 111 (Matter of Establishing the Japanese Pharmacopoeia; hereinafter referred to as "previous Pharmacopoeia"), issued in 2001, shall be abolished on March 31, 2006. However, in the case of drugs which are listed in the new Pharmacopoeia (limited to those listed in the previous Pharmacopoeia) and drugs which have been approved as of April 1, 2006 as prescribed under Paragraph 1, Article 14 of the same law [including drugs the Minister of Health, Labour and Welfare specifies (the Ministry of Health and Welfare Ministerial Notification No. 104, 1994) as those exempted from marketing approval pursuant to Paragraph 1, Article 14 of the Pharmaceutical Affairs Law (hereinafter referred to as "drugs exempted from approval")], the Name and Standards established in the previous Pharmacopoeia (limited to part of the Name and Standards for the drugs concerned) may be accepted to conform to the Name and Standards established in the new Pharmacopoeia before and on September 30, 2007. In the case of drugs which are listed in the new Pharmacopoeia (excluding those listed in the previous Pharmacopoeia) and drugs which have been approved as of April 1, 2006 as prescribed under Paragraph 1, Article 14 of the same law (including those exempted from approval), they may be accepted as those being not listed in the new Pharmacopoeia before and on September 30, 2007.

Jiro Kawasaki
The Minister of Health, Labour and Welfare

March 31, 2006

Referring the next title to this book: "The Japanese Pharmacopoeia".

(The text referred to by the term "as follows" are omitted here. All of them are made available for public exhibition at the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, at each Regional Bureau of Health and Welfare, and at each Prefectural Office in Japan).

*The term "as follows" here indicates the contents of the Japanese Pharmacopoeia Fifteenth Edition from General Notices to Ultraviolet-visible Reference Spectra (pp. 1 - 1654).

GENERAL RULES FOR PREPARATIONS

1. General Notices for Preparations

(1) General notices for preparations present general rules and definitions for pharmaceutical dosage forms.

(2) Pharmaceutical excipients are substance(s) other than drug substance(s) contained in preparations which are used to increase the utility of the preparation, to enable manufacturing of drug products easy, to keep product's integrity, to improve the appearance of a formulation and so forth. For these purposes, suitable excipients such as diluents, stabilizers, preservatives, buffering agents, corrigents, suspending agents, emulsifiers, aromatics, solubilizers, coloring agents, and viscous agents may be added. The excipients used, however, must be non-toxic, harmless and pharmacologically inactive in the amount administered and must not interfere with the therapeutic efficacy or the quality test of the preparations.

(3) Vegetable oils used for pharmaceutical preparations usually indicate the edible oils listed in the Pharmacopoeia. When starch is called for, any kind of starch incorporated in the Pharmacopoeia may be used, unless otherwise specified.

Moreover, ethanol specified in vol% is prepared by adding purified water or water for injection to ethanol at the specified vol%.

(4) To pharmaceutical preparations, functions which control the releasing rate of drug substance(s), leading to the modified absorption or transfer into the body may be added for the purpose of controlling the onset and duration of therapeutic effects and/or decreasing adverse or side effects. However, modified release preparations must meet the corresponding requirements of dissolution test etc. which specify the releasing rate, unless otherwise specified. In addition, the functional modification of releasing rate must be displayed on the pack insert and direct container or package of the preparation, unless otherwise specified.

(5) Immediate-release and modified-release preparations exist in oral dosage forms which show different release characteristics, respectively. Immediate-release dosage forms are preparations showing a release of drug substance(s), which is not intentionally modified and generally dependent on the intrinsic physicochemi-

cal properties of the drug substance. Modified-release dosage forms are preparations showing a release of drug substance(s) which is suitably modified by a specific formulation design and/or manufacturing method. Modified-release dosage forms include enteric-coated and extended release preparations. Enteric coated preparations are designed to release the majority drug substance(s) in small intestines rather than in stomachs in order to prevent the degradation or decomposition of drug substance(s) in stomach or to decrease the irritant effect of drug substance(s) on stomachs. Enteric coated preparations are generally prepared by applying enteric films to preparations. Extended release preparations are designed to control the releasing rate and time of drug substance(s) and the release sites in gastrointestinal tracts in order to decrease the dosing times and/or to reduce adverse or side effects. Extended release preparations are generally prepared using suitable agents that prolong the drug release. Capsules, tablets, powders, granules, and pills of oral dosage forms can be coated with appropriate coating agents, such as sugar, sugar alcohol, or high-molecular-mass materials to enable the ingestion easy or to prevent degradation of drug substance(s).

(6) When a high level of sterility assurance is maintained consistently, based on the records derived from validation studies of the manufacturing process and the in-process controls, the sterility test usually required for the release of the product may be omitted (Parametric release).

(7) Unless otherwise specified, preserve pharmaceutical preparations at room temperature.

2. Aerosols

(1) Aerosols are preparations for use by expelling a solution or suspension of drug substance(s) under a pressure of liquefied or compressed gas filled in a common or different container.

Aerosols are used for topical application, space spray, inhalation, oral administration, etc. Modes of expelling are available in vapor, powder, foam and paste, depending on the purpose of use.

(2) Hermetic containers are used for preservation.

3. Aromatic Waters

- (1) Aromatic Waters are clear saturated solutions of essential oils or other volatile substances in water.
- (2) Unless otherwise specified, Aromatic Waters may be usually prepared by the following process. Shake thoroughly 2 mL of an essential oil or 2 g of a volatile substance with 1000 mL of lukewarm purified water for 15 minutes, set the mixture aside for 12 hours or longer, filter through moistened filter paper, and add purified water to make 1000 mL. Alternatively, incorporate thoroughly 2 mL of an essential oil or 2 g of volatile substances with sufficient refined siliceous earth or pulped filter-paper, add 1000 mL of purified water, agitate thoroughly for 10 minutes, and then filter the mixture. To obtain a clear filtrate, repeat the filtration, and add sufficient water through the filter paper to make 1000 mL.
- (3) Aromatic Waters have odor and taste derived from the drug substance(s) and excipients used.
- (4) Tight containers are used for preservation.

4. Capsules

(1) Capsules are preparations in which liquefied, suspended, semi-solid, powdered or granulated drugs or preparations are enclosed in capsules or wrapped with capsule bases. There are two kinds of capsules, which are:

- (i) Hard capsules (ii) Soft capsules
- (2) Capsules are usually prepared by the following methods.

(i) Hard capsules: Drug substance(s) or uniform mixtures of drug substance(s) with diluents and other suitable excipients, or granules or preparations prepared by a suitable method, are filled as they are or prepared lightly formed and into hard capsules. Extended-release or enteric-coated capsules can be prepared by filling extended-release or enteric-coated preparations into capsules or by changing the components of capsule shells or coating the capsule with suitable coating agents.

(ii) Soft capsules: Drug substance(s) or mixtures of drug substance(s) with suitable diluents, etc. are enclosed by a suitable capsule such as gelatin plasticized by addition of glycerin, sorbitol, etc., and molded in a suitable shape. If necessary, coloring agents, preservatives, etc. may be added to capsule agents. By changing the components of capsule shells or applying suitable coating agents to capsules, extended-release or enteric-coated capsules can be prepared.

- (3) Unless otherwise specified, Capsules meet the

requirements of the Dissolution Test **<6.10>** or the Disintegration Test **<6.09>**.

- (4) Unless otherwise specified, Capsules meet the requirements of the Uniformity of Dosage Units **<6.02>**.

- (5) Well-closed or tight containers are used for preservation.

5. Cataplasms/Gel Patches

(1) Cataplasms/Gel Patches are generally pasty preparations containing the mixture of drug substance(s) and water or those prepared by spreading the mixture on cloth, which are intended for external use.

(2) Unless otherwise specified, Cataplasms/Gel Patches are usually prepared by mixing drug substance(s) with glycerin, water, or other suitable liquid materials, or with high-molecular-mass materials(s) which are soluble in water or absorbent of water until homogeneity is attained.

(3) Pasty cataplasms which have separated out one or more of their components during storage are rehomogenized before use unless the substances have deteriorated.

- (4) Tight containers are used for preservation.

6. Elixirs

(1) Elixirs are usually clear, sweetened, and aromatic liquid preparations, containing ethanol, intended for oral use.

(2) Elixirs are usually prepared by dissolving drugs or their extractives in ethanol and purified water, adding aromatic agents and sucrose, other sugars or sweetening agents, and clarifying by filtration or other procedures.

- (3) Tight containers are used for preservation.

7. Extracts

(1) Extracts are prepared by evaporating the extractives of crude drugs. There are two kinds of Extracts which are:

- (i) viscous extracts (ii) dry extracts

(2) Unless otherwise specified, Extracts are prepared as follows.

(i) Crude drugs pulverized in suitable sizes, are usually extracted for a certain period of time with suitable solvents by cold extraction or warm extraction, or by percolation as directed in (2) under Tinctures.

The extractive is filtered, and the filtrate is concentrated or dried in a suitable method to produce a millet jelly-like consistency in the case of a viscous extract, and to make crushable solid masses, granules or powder in the case of a dry extract.

Extracts for which the content of the drug substance(s) is specified are prepared by assaying the drug substance(s) in a sample portion and adjusting, if necessary, with suitable diluents to the specified strength.

(ii) Weigh crude drugs pulverized in suitable sizes according to the prescription and heat after adding 10 - 20 times water to them. After liquid-solid separation by centrifuge etc., the filtrate is concentrated or dried in a suitable method to produce a millet jelly-like consistency in the case of a viscous extract, and to make crushable solid masses, granules or powder in the case of a dry extract.

(3) Extracts have odor and taste derived from the crude drugs used.

(4) Unless otherwise specified, Extracts meet the requirements of the Heavy Metals Limit Test <1.07> when the test solution and the control solution are prepared as follows.

Test solution: Ignite 0.3 g of Extracts to ash, warm with 3 mL of the dilute hydrochloric acid, and filter. Wash the residue with two 5 mL portions of water. Neutralize the combined filtrate and washings (indicator: a drop of phenolphthalein TS) by adding ammonia TS until the color of the solution changes to pale red, filter, if necessary, and add 2 mL of the dilute acetic acid and water to make 50 mL.

Control solution: Proceed with 3 mL of dilute hydrochloric acid in the same manner as directed in the preparation of the test solution, and add 3.0 mL of Standard Lead Solution and water to make 50 mL.

(5) Tight containers are used for preservation.

8. Fluidextracts

(1) Fluidextracts are liquid percolates of crude drugs, usually prepared so that each mL contains soluble constituents from 1 g of the crude drugs.

(2) Fluidextracts are usually prepared by the percolation process. Mix well 1000 g of coarse powder or fine cutting of the crude drugs with the first solvent to moisten it, close the container, and allow it to stand for about 2 hours at room temperature. Transfer the content to a suitable percolator, stuff it as tightly as possible, open the lower opening of the percolator, and slowly pour the second solvent to cover the crude drugs. Close the lower opening when the solvent begins

to drop, and allow the mixture to stand for 2 to 3 days at room temperature. Open the lower opening, and allow the percolate to run out at the rate of 0.5 to 1.0 mL per minute.

Set aside the first 850 mL of the percolate as the first percolate. Add the second solvent to the percolator, then drip the percolate, and use it as the second percolate.

The time of maceration and the flow rate during percolation may be varied depending on the kind and the amount of the crude drugs used. The flow rate is usually regulated as follows, depending on the amount of the crude drugs used.

Mass of crude drug	Volume of solution running per minute
Not more than 1000 g	0.5 - 1.0 mL
Not more than 3000 g	1.0 - 2.0 mL
Not more than 10,000 g	2.0 - 4.0 mL

Concentrate the second percolate, taking care not to lose the volatile substances of the crude drug, mix with the first percolate, and use it as (A). To (A) add the second solvent to make 1000 mL, and allow the mixture to stand for 2 days. Decant the supernatant liquid or filter the liquid to obtain a clear solution.

Fluidextracts for which the content of the drug substance(s) is specified are obtained by adjusting the content of the drug substance(s) with a sufficient amount of the second solvent, as required on the basis of the result of the assay made with a portion of (A).

Use the specified solvent only in cases where there is no distinction between the first and the second solvent.

(3) Fluidextracts have odor and taste derived from the crude drugs used.

(4) Unless otherwise specified, Fluidextracts meet the requirements of the Heavy Metals Limit Test <1.07> when the test solution and the control solution are prepared as follows.

Test solution: Ignite 1.0 g of Fluidextracts to ash, warm with 3 mL of dilute hydrochloric acid, filter, and wash the residue with two 5 mL portions of water. Neutralize the combined filtrate and washings by adding ammonia TS, filter, if necessary, and add 2 mL of dilute acetic acid and water to make 50 mL.

Control solution: Proceed with 3 mL of dilute hydrochloric acid as directed in the preparation of the test solution, and add 3.0 mL of Standard Lead Solution and water to make 50 mL.

(5) Tight containers are used for preservation.

9. Granules

(1) Granules are prepared in a form of granules using drug substance(s) or a mixture of drug substance(s) and excipients.

(2) Granules are made, usually, from drug substance(s) or a uniform mixture of drug substance(s) with diluents, binders, disintegrators or other suitable excipients. The granules are prepared by a suitable method so that the finished granules are preferably equal in size. Extended-release or enteric coated granules can also be prepared by a suitable method.

(3) When the Particle Size Distribution Test *<6.03>* is performed with granules, all the granules pass through a No. 10 (1700 μm) sieve, not more than 5% of total granules remain on a No. 12 (1400 μm) sieve, and not more than 15% of total granules pass through a No. 42 (355 μm) sieve.

(4) Unless otherwise specified, Granules comply with the Dissolution Test *<6.10>* or the Disintegration Test *<6.09>*, provided that this provision does not apply to granules not more than 5% of which remain on a No. 30 (500 μm) sieve when shaken with a No. 30 sieve as directed under Particle Size Distribution Test *<6.03>*.

(5) Unless otherwise specified, Granules for single-dose use meet the requirements of the Uniformity of Dosage Units.

(6) Well-closed or tight containers are used for preservation.

10. Infusions and Decoctions

(1) Infusions and Decoctions are liquid preparations usually obtained by macerating crude drugs in purified water.

(2) Infusions and Decoctions are usually prepared by the following method. Cut crude drugs as directed below, and transfer 50 g to an infusion or decoction apparatus.

Leaves, flowers, and whole plants: Coarse cutting

Woods, stems, barks, roots, and rhizomes: Medium cutting

Seeds and fruits: Fine cutting

Infusions: Damp an amount of crude drugs with 50 mL of purified water for about 15 minutes, pour 900 mL of hot purified water, and heat for 5 minutes with several shakings. Filter through cloth after cooling.

Decoctions: Heat, with several stirrings, an amount of crude drugs with 950 mL of purified water for 30 minutes, and filter through cloth while warm.

Sufficient purified water is further added to the filtrate through the residue to make 1000 mL of an

infusion or decoction.

Prepare Infusions or Decoctions before use.

(3) Infusions and Decoctions have odor and taste derived from the crude drugs used.

(4) Tight containers are used for preservation.

11. Injections

(1) Injections are solutions, suspensions or emulsions of drugs or other preparations that contain drugs to be dissolved or suspended before use. They are sterile preparations to be administered directly into the skin or the body through the skin, or mucous membrane.

(2) Unless otherwise specified, Injections are prepared by dissolving, suspending or emulsifying drug substance(s) in a prescribed volume of the solvent, or by distributing drug substance(s) in hermetic containers for Injections. Every care should be taken to prevent contamination. The entire process of preparing Injections from the preparation of drug solution to the sterilization should be completed as rapidly as possible by taking into consideration the composition of Injection and the storage condition. The concentration of Injections expressed as % indicates w/v%.

Water for injection prepared by Reverse Osmosis-Ultrafiltration shall be sterilized by heating before use. This provision does not apply to Injections and attached solvent, if they are sterilized by heating in the process of manufacture.

Drugs to be dissolved or suspended before use and designated in the title as "for injection" may be accompanied by a suitable solvent.

(3) Solvents used in the preparation of Injections or attached to Injections must be harmless in the amounts usually administered and must not interfere with the therapeutic efficacy or with quality testing.

The solvents are classified into the following two major groups. They should meet the following requirements.

(i) Aqueous vehicles: As the solvent of aqueous injections, water for injection is usually used. Unless otherwise specified, isotonic sodium chloride solution, Ringer's solution, or other suitable aqueous solutions may be used instead. Unless otherwise specified, these aqueous vehicles other than those exclusively for intracutaneous, subcutaneous or intramuscular administration meet the requirements of the Bacterial Endotoxins Test *<4.01>*.

When the Bacterial Endotoxins Test *<4.01>* is not applicable to aqueous vehicles, the Pyrogen Test *<4.04>* may be used.

(ii) Non-aqueous vehicles: Vegetable oils are usually used as solvents for nonaqueous injections. These oils, unless otherwise specified, are clear at 10°C and have no odor or taste suggesting rancidity. The acid value is not more than 0.56, iodine value is between 79 and 137, and the saponification value falls in the range between 185 and 200. They meet the requirements of the Mineral Oil Test *<1.05>*.

Several suitable organic solvents other than the vegetable oils may be used as nonaqueous vehicles.

(4) The usual size of particles observed in suspensions for injection is not larger than 150 µm, and that of particles in emulsions for injection is not larger than 7 µm. As a rule, suspensions for injection are not to be injected into the vessels or spinal cord, and emulsions for injection, not into the spinal cord.

(5) Unless otherwise specified, any coloring agent must not be added solely for the purpose of coloring the preparations.

(6) Unless otherwise specified, sodium chloride or other suitable excipients may be added to aqueous injections to render them isotonic with blood or other body fluids. Acids or alkalis may be added to them to adjust the pH.

(7) Unless otherwise specified, sufficient amounts of suitable preservatives to prevent the growth of microorganisms are added to Injections filled in multiple dose containers.

(8) Unless otherwise specified, Injections other than those used exclusively for intracutaneous, subcutaneous or intramuscular administration meet the requirements of the Bacterial Endotoxins Test *<4.01>*.

When the Bacterial Endotoxins Test *<4.01>* is not applicable to Injections, the Pyrogen Test *<4.04>* may be used.

(9) Unless otherwise specified, Injections and solvents attached to Injections meet the requirements of the Sterility Test *<4.06>*.

(10) Usual containers of Injections are colorless and meet the requirements of the Glass Containers for Injections *<7.01>*. Where specified in individual monographs, these containers may be replaced by colored containers meeting the requirements of the Glass Containers for Injections *<7.01>* or by plastic containers for aqueous injections meeting the requirements of the Test Methods for Plastic Containers *<7.02>*.

(11) Unless otherwise specified, rubber stoppers used for glass containers of 100 mL or more of aqueous infusions meet the requirements of the Rubber Closures for Aqueous Infusions *<7.03>*.

(12) Unless otherwise specified, Injections meet the requirements of the Foreign Insoluble Matter Test for Injections *<6.06>*.

(13) Unless otherwise specified, Injections meet the requirements of the Insoluble Particulate Matter Test for Injections *<6.07>*.

(14) Unless otherwise specified, the actual volume of an injection contained in a single-dose container meets the requirements of Test for Extractable Volume of Parenteral Preparations *<6.05>*.

(15) Unless otherwise specified, Injections to be dissolved or suspended before use meet the requirements of the Uniformity of Dosage Units *<6.02>*.

(16) Unless otherwise specified, the written, printed, or graphic matter in the package, the container, or the wrapper must include the following information:

(i) Names of employed vehicles and added substance(s), unless the vehicle is water for injection, or sodium chloride solution in concentrations not exceeding 0.9 w/v%, or unless the vehicle contains acids or alkalies in order to adjust the pH of the injections.

(ii) In the case that dissolving vehicles are attached to the preparations, the presence of the vehicles and their names, quantities, compositions or ratios of the vehicles on the outer containers or outer wrappers.

(iii) Names and quantities of added stabilizers, preservatives, and diluents. In the case where nitrogen or carbon dioxide is enclosed in the container to replace the inside air, the statement of this replacement is not necessary.

(17) For ampules or other containers of 2 mL or less, the designations "injection", "for injection" and "aqueous suspension for injection" may be replaced by "inj.", "for inj." and "aq. susp. for inj.", respectively.

For ampules or other containers of more than 2 mL and not exceeding 10 mL, made of glass or similar materials, the designations "injection", "for injection" and "aqueous suspension for injection" may be replaced by "inj.", "for inj." and "aq. susp. for inj.", respectively, when information is printed directly on the surface of ampules or containers.

(18) Hermetic containers are used for preservation. Plastic containers for aqueous injections may be used when specified in an individual monograph.

12. Lemonades

(1) Lemonades are sweet, sour, and usually clear liquid preparations intended for oral use.

(2) Unless otherwise specified, Lemonades are usually prepared by dissolving hydrochloric acid, citric acid, L-tartaric acid, or lactic acid in simple syrup and purified water, and filtering if necessary.

Prepare Lemonades before use.

(3) Tight containers are used for preservation.

13. Liniments

(1) Liniments are usually liquid or semisolid preparations intended for external application to the skin by inunction.

(2) Unless otherwise specified, Liniments are usually prepared by adding drugs to water, ethanol, fatty oils, glycerin, soap, emulsifying agents, suspending agents, other suitable excipients or their mixtures, and kneading the mixture until homogeneity is attained.

(3) Liniments which have separated out one or more of their components during storage are rehomogenized before use unless the substances have deteriorated.

(4) Tight containers are used for preservation.

14. Liquids and Solutions

(1) Liquids and Solutions are liquid preparations intended for oral or external use. They are not identical with any other preparations under General Rules for Preparations.

(2) Liquids and Solutions are usually prepared directly with drug substance(s) or by dissolving drug substance(s) in a solvent.

(3) Tight containers are used for preservation.

15. Lotions

(1) Lotions are external preparations applied to the skin by inunction, which are usually prepared by dissolving drug substance(s) in an aqueous vehicle or emulsifying or dispersing them homogeneously.

(2) Unless otherwise specified, Lotions are usually prepared by adding drug substance(s) with solvents, emulsifying agents, suspending agents, etc. to an aqueous vehicle and mixing to complete uniformity by a suitable method.

Prepare before use in the case of Lotions which are apt to deteriorate.

(3) Lotions which have separated out one or more of their components during storage are rehomogenized before use unless the substances have deteriorated.

(4) Tight containers are used for preservation.

16. Ointments

(1) Ointments are usually homogeneous, semisolid preparations for external application, of such consistency that they may be applied to the skin by inunction.

(2) Unless otherwise specified, Ointments are usually prepared by kneading and mixing homogeneously drug substance(s) with fats, fatty oils, lanolin, petrolatum, paraffin, waxes, resins, plastics, glycols, higher alcohols, glycerin, water, emulsifying agents, suspending agents, or other suitable excipients, or with above excipients emulsified in a suitable way as bases.

Prepare before use in the case of Ointments which are apt to deteriorate.

Ointments which are prepared with emulsified bases may be described as Cream.

(3) Ointments are free from rancid odor.

(4) Tight containers are used for preservation.

17. Ophthalmic Ointments

(1) Ophthalmic Ointments are aseptic ointments intended for the application to the conjunctiva.

(2) Ophthalmic Ointments are usually prepared by the following method. Solution of drug substance(s) or finely powdered drug substance(s) are thoroughly mixed with petrolatum or other suitable materials as a base, and are distributed into collapsible tubes or other tight containers. Sufficient care should be taken to prevent any kinds of contamination, and to proceed as fast as possible in the manufacturing of products.

(3) The particle size of drug substance(s) in Ophthalmic Ointments is usually not larger than 75 μm .

(4) Unless otherwise specified, Ophthalmic Ointments meet the requirements of the Sterility Test <4.06>, and unless otherwise specified, carry out the test by the Membrane filtration method.

(5) Unless otherwise specified, Ophthalmic Ointments meet the requirements of the Test of Metal Particles in Ophthalmic Ointments <6.01>.

The requirement is met if a total of not more than 50 metal particles, each measuring 50 μm or more in any dimension, is found in the 10 samples, and if not more than one sample is found to contain more than 8 such particles. If Ophthalmic Ointments fail the foregoing test, repeat the test on 20 additional samples of Ophthalmic Ointments. The requirement is met if a total of not more than 150 metal particles, each measuring 50 μm or more in any dimension, is found in the 30 samples, and if not more than three samples are

found to contain more than 8 such particles each.

(6) Tight containers are used for preservation.

18. Ophthalmic Solutions

(1) Ophthalmic Solutions are aseptic preparations intended for application to the conjunctiva. They are solutions or suspensions of the drug substance(s), or preparations which contain drug substance(s) to be dissolved or suspended before use.

(2) Unless otherwise specified, Ophthalmic Solutions are prepared either by dissolving or suspending drug substance(s) in a prescribed volume of a solvent, or by placing drug substance(s) in tight containers. Every caution is required to avoid contamination in preparing Ophthalmic Solutions. The entire process of preparing Ophthalmic Solutions should be completed as rapidly as possible. The concentration of Ophthalmic Solutions expressed as % of a drug substance indicates w/v%.

Preparations to be dissolved or suspended before use and designated as "for ophthalmic solutions" may be accompanied by a suitable solvent.

(3) Solvents used in the preparation of Ophthalmic Solutions or attached to Ophthalmic Solutions must be harmless in the amounts usually administered and must not interfere with therapeutic efficacy, or with testing.

Solvents for Ophthalmic Solutions are classified into the following two major groups. They should meet the following requirements.

(i) Aqueous vehicles: The usual vehicle for aqueous ophthalmic solutions is purified water or suitable aqueous solutions. Solvents constituted to Ophthalmic Solutions are sterilized, purified water or suitable sterilized aqueous solutions.

(ii) Non-aqueous vehicles: The vehicles for non-aqueous ophthalmic solutions are usually vegetable oils. Also, suitable organic solvents may be used as non-aqueous solvents for some preparations.

(4) The usual particle size observed in suspensions for Ophthalmic Solutions is not larger than 75 μm .

(5) Unless otherwise specified, no coloring agent may be added solely for the purpose of coloring the preparations.

(6) Unless otherwise specified, sodium chloride or other suitable excipients may be added to aqueous preparations to render them isotonic with lachrymal liquid. Acids or alkalies or other suitable excipients, may be added to aqueous preparations to adjust the pH.

(7) Unless otherwise specified, Ophthalmic Solutions and solvents attached to Ophthalmic Solutions

meet the requirements of the Sterility Test <4.06>.

(8) Ophthalmic Solutions prepared as aqueous solution and aqueous vehicles attached to Ophthalmic Solutions to be prepared before use should be clear and free from foreign insoluble matter when inspected with the unaided eye at a position of luminous intensity of 3000 to 5000 luxes under an incandescent electric bulb. The containers of Ophthalmic Solutions should have a transparency which does not interfere with the test for foreign matter.

(9) Unless otherwise specified, Ophthalmic Solutions meet the Insoluble Particulate Matter Test for Ophthalmic Solutions <6.08>. The limit of the particulates is not more than 1 particle per mL equal to or greater than 300 μm .

(10) Tight containers are used for preservation.

19. Pills

(1) Pills are spherical masses.

(2) Pills are usually prepared by mixing drug substance(s) uniformly with diluents, binders, disintegrators or other suitable excipients, and rolling into spherical form by a suitable method.

(3) Unless otherwise specified, Pills comply with the Dissolution Test <6.10> or the Disintegration Test <6.09>.

(4) Well-closed or tight containers are used for preservation.

20. Plasters and Pressure Sensitive Adhesive Tapes

(1) Plasters and Pressure Sensitive Adhesive Tapes are usually used as topical drugs of external use by spreading or sealing a mixture of drug substance(s), bases and excipients on a cloth or on/in a plastic film, and adhering to the skin in order to deliver the drug substance(s) to the disease sites located to the skin or nearby skin.

(2) Unless otherwise specified, Plasters and Pressure Sensitive Adhesive Tapes are usually prepared by mixing bases such as water soluble or insoluble, natural or artificial high-molecular-mass compound, or their mixture uniformly with drug substance(s) and kneading or sealing on a cloth or film into a suitable shape.

Unless otherwise specified, Plasters and Pressure Sensitive Adhesive Tapes prepared from fats, fatty oils, salts of fatty acids, waxes, resins, plastics, purified lanolin, rubber, or a mixture of the above substances, or prepared by mixing the drug substance(s) with the

above bases uniformly and as a solid at the ordinary temperature, may be described as plasters.

(3) Well-closed containers are used for preservation.

21. Powders

(1) Powders are preparations in powdered or finely granulated form.

(2) Powders are usually prepared by uniformly mixing drug substance(s) with or without diluents, binders, disintegrators or other suitable excipients by a suitable method to produce a pulverized or finely granulated form.

(3) When the Particle Size Distribution Test <6.03> is performed with Powders, all the powders pass through a No. 18 (850 μm) sieve and not more than 5% of total powders remain on a No. 30 (500 μm) sieve. Powders with not more than 10% of total passing through a No. 200 (75 μm) sieve may be described as Fine Granules.

(4) Unless otherwise specified, Powders for single-dose use meet the requirements of the Uniformity of Dosage Units <6.02>.

(5) Well-closed or tight containers are used for preservation.

22. Spirits

(1) Spirits are usually alcoholic or hydro-alcoholic solutions of volatile drug substance(s).

(2) Unless otherwise specified, Spirits are usually prepared by dissolving drug substance(s) in ethanol or in a mixture of ethanol and water.

(3) Tight containers are used for preservation, removing from fire.

23. Suppositories

(1) Suppositories are solid preparations intended for insertion into the rectal or vaginal cavity. Suppositories are usually prepared by molding bases into a suitable shape.

Suppositories melt or soften at body temperature or dissolve slowly in the secretions.

(2) Unless otherwise specified, Suppositories are usually prepared by mixing drug substance(s) with fat-type bases, watermiscible bases or other suitable materials, and, if necessary, with emulsifying agents, suspending agents, etc. into a homogeneous mass, and

molding it into a suitable shape or coating it with a suitable coating agent, or prepared as a liquid form-fill-seal.

(3) Rectal suppositories are usually conical or spindle-shaped, and Vaginal suppositories are globular or oval.

(4) Unless otherwise specified, Suppositories meet the requirements of the Uniformity of Dosage Units <6.02>.

(5) Well-closed or tight containers are used for preservation.

24. Suspensions and Emulsions

(1) Suspensions and Emulsions are usually liquid preparations of finely divided drug substance(s) suspended or emulsified uniformly in liquid vehicles, respectively.

(2) Suspensions and Emulsions are usually prepared by the following method.

Suspensions: Suspensions are prepared by adding suspending agents or other suitable excipients and purified water or oil to drug substance(s), and suspending to complete uniformity by a suitable method.

Emulsions: Emulsions are prepared by adding emulsifying agents and purified water to drug substance(s), and emulsifying to complete uniformity by a suitable method.

If necessary, preservatives, stabilizers, etc., may be added.

Prepare before use in the case of Suspensions or Emulsions which are apt to deteriorate.

(3) Mix uniformly before use, if necessary.

(4) Tight containers are used for preservation.

25. Syrups

(1) Syrups are oral liquid preparations. Syrups are solutions of sucrose, or viscous liquids or suspensions of drug substance(s) containing sucrose, other sugars or sweetening agents.

Syrups include the preparations which are dissolved or suspended before use depending on the properties of the drug substance(s).

(2) Unless otherwise specified, Syrups are usually prepared by dissolving, mixing, suspending or emulsifying drug substance(s) in solutions of sucrose, other sugars or sweetening agents, or in simple syrup. If necessary, the mixtures are boiled and filtered while hot.

(3) Unless otherwise specified, Syrups which are

dissolved or suspended before use and are for single-dose use (divided dosage forms) meet the requirements of the Uniformity of Dosage Units [<6.02>](#).

(4) Tight containers are used for preservation.

26. Tablets

(1) Tablets are prepared by compressing drug substance(s) directly, or by forming or molding drug substance(s) dampened with a solvent into a desired shape and size. Sugar- and film-coated tablets can be prepared by coating core tablets using suitable coating agents containing sugars, sugar alcohols and related substances and by coating with thin films using suitable film coating agents, respectively. Enteric coated and extended release tablets can be prepared by suitable methods.

(2) Tablets are usually prepared by the following procedures:

(i) Drug substance(s) are first rendered granular in a suitable method with or without uniform admixture with a diluent, binder, disintegrator, and other suitable excipients. The resultant granules are provided with additives such as a lubricant, and compressed into a desired shape and size.

(ii) Tablets may also be prepared either by direct compression of drug substance(s) with or without a diluent, binder, disintegrator, and other suitable excipients; or by compression after drug substance(s) with or without suitable excipients have been added to previously prepared inactive granules.

(iii) Tablets may also be prepared by drying the admixture by a suitable method after forming or molding drug substance(s), uniformly mixed with a diluent, binder and other suitable excipients and dampened with a solvent, into a desired shape and size.

(iv) Multilayer tablets can be prepared by compressing different layers of particles or granules in composition. Press-coated tablets can be prepared by covering inner core tablets with different layers in composition by a suitable method.

(3) Unless otherwise specified, Tablets meet the requirements of the Dissolution Test [<6.10>](#) or the Disintegration Test [<6.09>](#).

(4) Unless otherwise specified, Tablets meet the requirements of the Uniformity of Dosage Units [<6.02>](#). The requirements for coated tablets are provided in each monograph.

(5) Well-closed or tight containers are used for preservation.

27. Tinctures

(1) Tinctures are liquid preparations, and usually prepared by extracting crude drug substance(s) with ethanol or with a mixture of ethanol and purified water.

(2) Unless otherwise specified, Tinctures are usually prepared from coarse powder or fine cuttings of crude drug substance(s) either by maceration or by percolation as described below.

Maceration: Place crude drugs in a suitable container, and add about three-fourths of the total volume of a solvent to be used. Stopper, and allow the container to stand at ordinary temperature with occasional stirring for about 5 days or until the soluble constituents have satisfactorily dissolved. Filter the liquid through cloth. Wash the residue with several portions of the solvent, and press. Combine the filtrate and washings, and add sufficient solvent to make up the volume. Allow the mixture to stand for about 2 days, and obtain a clear liquid by decantation or filtration.

Percolation: Pour the solvent in small portions on crude drugs placed in a container, and mix well to moisten the crude drugs. Stopper the container, and allow it to stand for about 2 hours at room temperature. Pack the contents as tightly as possible in a suitable percolator, open the lower opening, and slowly pour sufficient solvent to cover the crude drugs. When the percolate begins to drip, close the opening, and allow the mixture to stand for 2 to 3 days at room temperature. Open the opening, and allow the percolate to drip at a rate of 1 to 3 mL per minute. Add an appropriate quantity of the solvent, and continue to percolate until the desired volume has passed. Mix thoroughly, allow standing for 2 days, and obtain a clear liquid by decantation or filtration. The time of standing and the flow rate may be varied depending on the kind and amount of crude drugs to be percolated.

Tinctures prepared by either of the above methods for which the content of the drug substance is specified are prepared by assaying the drug substance using a portion of the sample and adjusting, if necessary, with the percolate or with the solvent to the specified content.

(3) Tight containers are used for preservation, remote from fire.

28. Transdermal Systems

(1) Transdermal Systems are preparations applied to the skin that are designed to deliver drug substance(s) through the skin to the systemic blood circulation.

Transdermal Systems include semisolid mixtures of drug substance(s) and excipients which are used by spreading a suitable amount of the mixture on the backing layer.

(2) Unless otherwise specified, Transdermal Systems are usually prepared by spreading the mixtures of emulsified or suspended drug substance(s) and soluble or insoluble high molecular weight of natural or synthetic bases or their mixtures on the liner or backing sheet. If necessary, adhesives agents, solvents or skin permeation enhancers etc., may be added. The transdermal systems are also prepared by filling the mixture of drug substance(s) and bases or excipients in a reservoir made of a backing layer and a membrane which controls the release of drug substance(s).

(3) Transdermal Systems meet the requirements of release tests specified.

(4) Well-closed or tight containers are used for preservation.

29. Troches

(1) Troches are usually preparations of suitable shape to dissolve or disintegrate slowly in the mouth, and are intended for application to the mouth or the throat.

(2) Troches are usually prepared by the following procedures:

(i) Drug substance(s) are first rendered granular by a suitable method with or without uniform admixing with a diluent, binder, and other suitable excipients. The resultant granules are provided with additives such as a lubricant, and compressed into a desired shape and size.

(ii) Troches may also be prepared either by direct compression of drug substance(s) with or without a diluent, binder or other suitable excipients, or by compression of drug substance(s) with or without suitable excipients after they have been uniformly mixed with previously prepared inactive granules.

(iii) Troches are also prepared by mixing drug substance(s) with a diluent such as sucrose, binder, moistening agent, other suitable excipients, etc., to make a homogeneous paste, spreading the paste, stamping out or cutting into a suitable shape and drying.

(3) Unless otherwise specified, Troches meet the requirements of the Uniformity of Dosage Units <6.02>.

(4) Well-closed or tight containers are used for preservation.

Application No.: 10/591,164

Docket No. : 2006_1328A

EXHIBIT 2

(4 pages total, including cover)

Appendix 3

Solar Energy Charity

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Tylenol

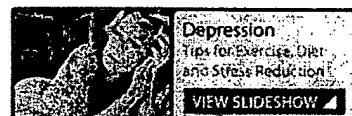
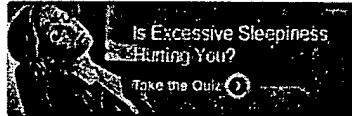
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 « previous [1] 2 3 4 5 6 7 8 9 10 11 12 13 next »

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Tylenol

 Fibromyalgia Friendly Exercises Slideshow 

Depression Tips for Stress Reduction Slideshow 



Drug Description

FONT
SIZE
A A A

TYLENOL® (acetaminophen)

DRUG DESCRIPTION

American Hospital Formulary Service (Ahfs)* Classification Number

28:08.92

Generic Name

USAN: acetaminophen

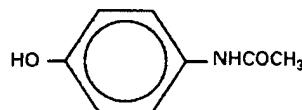
INN: paracetamol CAS#: 103-90-2

Source of Supply (Trade Name and Manufacturer)

TYLENOL® (acetaminophen) - McNeil Consumer Healthcare

Physical Properties Of The Chemical Entity¹

a. Structural Formula



b. Molecular Formula

C₈H₉NO₂

c. Molecular Weight

151.16

d. Macroscopic Appearance

Acetaminophen is a white, crystalline powder.

e. Solubility

water 1:70
 boiling water 1:20
 alcohol 1:10
 chloroform 1:50
 glycerin 1:40
 ether slightly soluble

Chemical Properties

a. Structural Similarities/Differences of the Drug to Other Available Compounds or Groups of Compounds

Acetaminophen is a synthetic, nonopiate, centrally acting analgesic derived from *p*-aminophenol. The full chemical name is N-acetyl-*p*-aminophenol.

b. pKa

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Coping With RA Pain: Tips for Women
 9 Painful Symptoms of Depression

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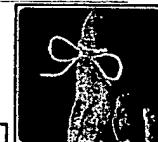
Fibromyalgia Center

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Alzheimer's Caregiver's Guide



Recommended Topic Related To:
 Tylenol

The pKa of acetaminophen is 9.51 at 25°C.

c. Stability of the Drug to Temperature, Light, and Moisture

Acetaminophen is stable to temperature, light, and moisture.

d. pH Range Over Which Drug is Stable in Solution

Acetaminophen is stable at a pH between 4 and 7 at 25°C.

e. pH of Commercially Available Liquid Products

Acetaminophen oral solution (ie, elixir, adult liquid) has a pH of 3.8 to 6.1 and the oral suspension (ie, infants' drops, children's suspension) has a pH of 5.4 to 6.9.

f. Osmolarity/Osmolality of Commercially Available Solutions

Extra Strength TYLENOL® acetaminophen Adult Liquid: 3058 ± 152 mmol/kg

Children's TYLENOL® acetaminophen Elixir: 6040 ± 25 mmol/kg

Because of the nature of suspension formulations, osmolarity of the TYLENOL® acetaminophen suspension products cannot be determined.

References

1. Remington's Pharmaceutical Sciences, 23rd ed. Easton, PA: Mack Publishing Company; 1995:1109-1110.

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1 Tylenol User Reviews

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Application No.: 10/591,164

Docket No. : 2006_1328A

EXHIBIT 3

(6 pages total, including cover)

Which oral solid medications should be protected from light and/or moisture?

Jack M. Rosenberg, Pharm.D, Ph.D., Sara Schilit, Pharm.D, Joseph P. Nathan, M.S., Pharm.D.

Recently, the International Drug Information Center (IDIC) of the Arnold & Marie Schwartz College of Pharmacy and Health Sciences, Long Island University, received an inquiry from a consulting firm that provides services in a pharmacy that prepares unit-dose packaged medications for institutional use. The consultant requested a list of light-sensitive and moisture-sensitive prescription oral solid dosage forms. After searching the literature (tertiary references, MEDLINE, International Pharmaceutical Abstracts, Internet), we failed to identify such a list. We therefore proceeded to compile our own list of these medications. The list was compiled by using *Facts and Comparisons* 4.0, available at www.factsandcomparisons.com, and the online *Physician's Desk Reference*, available at www.pdr.net, using the Advanced Search functions. These databases are restricted databases, but are available at the IDIC. The search was performed using the term "light" and was then repeated with the term "moisture." The search yielded an extensive list of drug monographs, with each monograph bearing at least one of the search terms. Each monograph was then analyzed to determine whether it states that the medication necessitates protection from light or moisture, or is light- or moisture-sensitive. The compilation consists of 300 medications, of which 233 are light-sensitive and 146 are moisture-sensitive. The authors extend their gratitude to Alex Antonopoulos, Pharm.D., candidate; Raghavendra Chede, Pharm.D., candidate; Karina Muzykowsky, Pharm.D., candidate; and Maitri Trivedi, Pharm.D., candidate, for their assistance in preparing this list.

JACK M. ROSENBERG is Professor of Pharmacology and Pharmacy Practice, Director, International Drug Information Center; SARA SCHILLIT, Drug Information Specialist; and Adjunct Assistant Professor of Pharmacy Practice, and JOSEPH P. NATHAN is Assistant Professor of Pharmacy Practice, Arnold & Marie Schwartz College of Pharmacy and Health Sciences, Long Island University.

Generic Name	Brand Name	Light Sensitive	Moisture Sensitive
Acetazolase	Freaze		
Acetaminophen - codeine phosphate	Sedard		
Acetaminophen + hydrocodone bitartrate	Vicodin, Zydol		
Acetazolamide	Diamox, Sequels		
Acitretin	Soriatane		
Acyclovine	Zovirax		
Acetazolamide sodium - cholecalciferol	Fosomex plus D		
Aluzene HCl	Uroxat		
Alzenan	Teklura		
Alprenolol	Zloprom, Alupurin		
Alprenolol	Lopressor		
Alprazolam	Xanax		
Amantadine hydrochloride	Symmetrel		
Amantadine hydrochloride	Mitramer		
Amantadine hydrochloride	Mitramine		
Aminoglycosides	Cyclader		
Amiodarone	Cardizem, Propafenone		
Amiflrylicine	Eltai		
Amiflrylicine	Nonine, Amoz		
Amiodarone and benzopropenyl hydrochloride	Lofrel		
Amiodarone and ketotifen	Extrage		
Amiodarone and desmethylphenamine salts	Adeseril XR		
Amiflrylicine HCl	Agnyn		
Amiflrylicine and dipropandamide	Aquerox		
Amiflrylicine	Tenoxin		
Amorphous sulfate, hyoscymamine hydrochloride, theophylline succinate hydrochloride	Dornatol		
Amoxolin	Ridour		
Amiflrylicine	Azason		
Amiflrylicine hydrochloride	Loferol		
Amiflrylicine hydrochloride and hydrochlorothiazide	Loferol HCT		
Amoxapine	Tessalon		
Amoxapine	Targen		
Amoxapine	Alavutin		
Generic Name	Brand Name	Light Sensitive	Moisture Sensitive
Biphasophomate combination	Fosamax Plus D		
Desipramine hydrochloride	Zeloxin		
Domperidone mesylate	Peribid		
Dunmetolide	Dunex		
Dypirone (Ibuprofenide)	Wolbulon		
Dysprine	Drenza		
Cabergol	Pocadol		
Cabotanib	Cab-Lac		
Captopril	Captoten		
Captopril and hydrochlorothiazide	Cresartan		
Catenazepine	Eptol, Fegesol		
Catentemazepine extended-release	Catolard, Eptero		
Catibamazine	Palgo, Hstec (C)		
Cativerol	Corg		
Cefdinir pivoxil	Spectinol		
Cefpodoxime	Vantin		
Chlordiazepoxide	Lorazin		
Chloroquine phosphate	Ardu, Phosphate		
Chlorpromazine	Thixazine		
Chlorpromazine	Pharax, Remuler-S, Pardon Forte (NS)		
Chlorzic	Fapmel		
Clarithromycin	Dayon		
Clomiphene Citrate	Clomid, Miganova, Serophene		
Clomipramine hydrochloride	Amatral		
Clonazepam	Klonop		
Clonidine	Caterves		
Clorazepate hydrochloride and chinolodidone	Umpres		
Clorazepate dipotassium	Tranxene		
Clorazepine	Clexar, Fazod		
Codeine phosphate and codeine sulfate	Codeine		
Coldstream hydrochloride	Weldol		
Colistec	Colistore		
Colistore	Bourne, Waveare		
Colchicine hydrochloride	Flent, Flent, Anna		
Cysteamine bitartrate	Cystagon		

Generic Name	Brand Name	Light Sensitive	Moisture Sensitive
Diazox	Diazox		
Diazepam	Eztox		
Isosox	Euide		
Dibazaine	Carne		
Dibazaine and oxazol extremo	Carne-D		
Diaminopentane hydrochloride	Fuzin		
Dextromethorphan	DextroSol		
Diazepam	Velum		
Diazox	Diazox		
Dicumarol (dicoumarin)	Veloxen		
Dicumarol sodium	Cadexin, Xadexin		
Dicumarol hydrochloride	Dexyl, Dicumarine		
Diphenox	Lomotil		
Diphenox (Cetene, Cetia, Tafia, Tesci, Diros)			
Diphenox	Tacox		
Diphenox	Argenex		
Diphenox	Asimex, Peacock, Vena, Vena-Lax, Quiv, Moreco, Viz, Laxogen		
Diphenox	Vintec		
Diphenox hydrochloride and isoxizole	Lomox		
Diphenox	Bradutol		
Diphenox mesylate	Diphenox mesylate		
Diphenox mesylate	Frodoate		
Diphenox	Hypon		
Diphenox mesylate	Ery-lax N, Dexamol, End.		
Diphenox mesylate	FFS		
Diphenox	Farmox (Tyrold, Furox)		
Diphenox	Ogen		
Diphenox	Zimox		
Diphenox	Endox		
Diphenox	Indox		
Diphenox	Zeta		
Diphenox	Syphn		
Diphenox	Repol		
Diphenox	Revol		

Generic Name	Brand Name	Light Sensitive	Moisture Sensitive
Fenobiprole	Trice, Triclo, Liofira, Arian		
Fenoxylolol	Fentha		
Fenoxylolol	Hemoxyl, Feretek, Naphrofer Fenoxylolol		
Fenoxylolol	Proxen Proxer		
Fenoxylolol	Lumibel		
Fenoxylolol	Proxac		
Fenoxylolol hydrochloride	Rupheazine		
Fenoxylolol	Fharinde		
Fenoxylolol	Uscol		
Fenoxylolol	Demix, Fohne		
Fenoxylolol sodium	Monomil		
Fenoxylolol sodium	Iron		
Fenoxylolol	See		
Fenoxylolol	Faztre		
Fenoxylolol	Fluxtrid		
Fenoxylolol	Glucovance		
Fenoxylolol	Wid		
Fenoxylolol	Gro-Fel		
Fenoxylolol	Tenox		
Fenoxylolol	Hedol		
Fenoxylolol hydrochloride hydrochloride	Hicuvan		
Fenoxylolol	Acospine		
Fenoxylolol hydrochloride	Hydrofugal, Hydrofug, Endo, Meracida		
Fenoxylolol	Veromol		
Fenoxylolol	Dibund		
Fenoxylolol sulfate	Novozol		
Fenoxylolol	Isol		
Fenoxylolol	Citran		
Fenoxylolol	Indoon		
Fenoxylolol	Hydrox		
Fenoxylolol	Endo, Thalose, Endo, Delgate		
Fenoxylolol	Monozel, Indu		
Fenoxylolol	Accutane, Amnesteem, Colox, Simep		
Fenoxylolol	Lynoxic		

Generic Name	Brand Name	Light Sensitive	Moisture Sensitive
Isoproterenol	Sproster		
Ketopropane	Noral		
Ketoprofen	Ketoprofen		
Labetal hydrochloride	Normodine, Triandate		
Lamotrigine	Lamidal		
Lancoprazole	Pizax		
Lansoprazole amoxicilin and clarithromycin	Premix		
Lanthanum carbonate	Frozent		
Leftinuride	Avera		
Leucovorin calcium	Leucovorin		
Levorotetrahydroxybutyrate	Silene, Paroxa		
Levothyroxine sodium	Synthroid		
Lidocaine	Acresol, ED-SPM2, Lido, Syner, Nenol, Minisys, Lymex		
Lisosid	Zyox		
Lidocaine tetramine	Wynave		
Lengol	Prind, Zezu		
Lengol hydrochloride	Fenetic		
Lithium	Lithobut		
Lorazepam	Azran		
Losartan potassium	Corza		
Lowestol	Mexcor		
Magnesium salicylate	Novosal		
Magnolol	Magnolino		
Meloxic	Akvel		
Melenamic acid	Porel		
Mephaden	Alavan		
Meprobenemate sulfate	Alperi		
Mephazepine	Mephazepine		
Mebazin	Forxet, Glucophage		
Meladone	Dokchine		

Generic Name	Brand Name	Light Sensitive	Moisture Sensitive
Methenethiolate hydrochloride	Desopin		
Methimazine hydrochloride	Urex		
Melocurine	Retoxin		
Melotrate	Melotrate		
Methiamide	Cordrin		
Methylenovine methylene	Velergue		
Methylbenzethonium chloride	Concerta, Reldin		
Methocarbamol	Regan		
Methocarbamol	Zanelyn		
Methocarbamol	Lopressor		
Methohexitol	Regil		
Minoxidil	Suboxil		
Mixazine	Remoxin		
Mixazone	Unics		
Mixazone	Melan		
Mixazone	Singular		
Mixazine	Elmazine		
Mixazine	Kaden, M's Contin		
Mixazine	Mixofus, Cetax		
Mixazone	Lengard		
Mixazine hydrochloride	Refa		
Mixazone	Ampro		
Mixazone and triquazac	Triacid, Mixapac		
Mixazone	Dystic		
Mixazone	Mefazone		
Mixazine	Amazone		
Mixazine	Nitrom		
Mixazine	Mixolop		

Generic Name	Brand Name	Light Sensitive	Moisture Sensitive
Neodol	SAB		
Hekogen	Neogard		
Neotone	AN		
Neotolyl	Prinol		
Nyston	Meustan		
Okapure	Zinea		
Omeprazol/Amoteky disulfur	Synox		
Omeprazole	Prilosec		
Ondansetron	Zofin		
Otsuka	Xeljel		
Oxytropin	Urope		
Oxytropinolide	Otropin		
Oxytropine	Oxytropin		
Oxytropine/Amoteky disulfur	Synox		
Oxytropinolide	Prilosec		
Oxytropinolide	Neogard		
Oxytropinolide	Neotolyl		
Oxytropinolide(PIU)	Propriobacter(PIU)		
Oxytropine	Danpon		
Oxazepam	Cord		
Oxendol	Accord		
Oxindole Sulfate	Oxiquin		
Oxipendazole	Antara		
Oxipendazole	Recepto		
Oxipendazole	Prandin		
Oxipendazole	Relekt		
Oxipendazole/oxindole calumin/cetene	Actimed/oxindole/Calumin		
Oxipendazole	Recepto		
Oxone	Now		
Oxyprin hydrochloride	Repin		
Oxytropine	Agendin		
Oxytropine/glycine	Avanant		
Oxytropine/mefim	Avanand		
Oxymestolactum	Oxetor		
Oxytropin hydrochlori- de	Naran		
Oxytropine	Dolpon/Zapar		
Oxytropine	Pengyl		
Oxytropine hydrochloride	Merid		
Oxytropine	Pavamure		
Oxytropine hydrochloride	Obupare		
Oxytropine	Adactone		
Oxytropine	Zen		
Oxytropine	Sildadore		
Oxytropine hydrochloride	Cigrex		
Oxytropine hydrochloride	Nikade		
Oxytropine	Rektor		
Oxytropine	Hytan		
Oxytropine	Leng		
Oxytropine	Obeline		
Oxytropine hydrochloride	Sunyon		
Oxytropine	Thalomid		

Generic Name	Brand Name	Light Sensitive	Moisture Sensitive
Oxytropine	Prandin		
Promethazine	Phenegran		
Promethazine bromate	Ro-Gardine		
Promethadol	Obelin		
Promethadol(PIU)	Propriobacter(PIU)		
Promethamine	Danpon		
Promethazine	Cord		
Promethazine	Accord		
Promethazine Sulfate	Oxiquin		
Promethazine	Antara		
Promethazine	Recepto		
Promethazine	Prandin		
Promethazine	Relekt		
Promethazine/oxindole calumin/cetene	Actimed/oxindole/Calumin		
Promethazine	Recepto		
Promethazine	Now		
Promethazine hydrochloride	Repin		
Promethazine	Agendin		
Promethazine/glycine	Avanant		
Promethazine/mefim	Avanand		
Promethazine	Oxetor		
Promethazine	Naran		
Promethazine	Dolpon/Zapar		
Promethazine	Pengyl		
Promethazine hydrochloride	Merid		
Promethazine	Pavamure		
Promethazine hydrochloride	Obupare		
Promethazine	Adactone		
Promethazine	Zen		
Promethazine	Sildadore		
Promethazine hydrochloride	Cigrex		
Promethazine hydrochloride	Nikade		
Promethazine	Rektor		
Promethazine	Hytan		
Promethazine	Leng		
Promethazine	Obeline		
Promethazine hydrochloride	Sunyon		
Promethazine	Thalomid		

Generic Name	Brand Name	Light Sensitive	Moisture Sensitive
Terophylline	Theotulen		
Thionazene	Thionazene		
Thiotrione	Thizolene		
Thyrol	Amico thyroid		
Thioguanine hydrochloride	Gath		
Timadol maleate	Timold		
Timolol maleate	Timolol		
Timolol maleate	Thulense		
Tolmein	Tolmein		
Trifluoclofene	Derrill A		
Topramide	Topram		
Toprecon	Hyconin		
Turamidone	Frisson		
Trizadore	Dosyel		
Trizadore	Vesund		
Trizadore	Oxylum		

Generic Name	Brand Name	Light Sensitive	Moisture Sensitive
Tramadol hydrochloride	Doxidol		
Trimelodienamide	Tigas		
Timethonium hydrochloride	Phagom		
Vobstrol	Obien		
Vobstrol hydrochloride	Obien HCT		
Wiemers	Neophyton		
Wieland Sodum	Coumedin		
Zantac	Acidale		
Zaledon	Soreta		
Zeluton	Zilo		
Zimelidine	Gordon		
Zimeldine	Retrow		
Zimelidine	Zomig		
Zimelidine	Zomig		

Drug Topics

May 12, 2008

Clinical Q & A: Which oral solid medications should be protected from light and/or moisture?

By Jack M. Rosenberg, PharmD, PhD, Sara Schilit, PharmD, Joseph P. Nathan, MS, PharmD

Recently, the International Drug Information Center (IDIC) of the Arnold & Marie Schwartz College of Pharmacy and Health Sciences, Long Island University, received an inquiry from a consulting firm that provides services to a pharmacy that prepares unit-dose packaged medications for institutional use. The consultant requested a list of light-sensitive and moisture-sensitive prescription oral solid dosage forms. After searching the literature (tertiary references, MEDLINE, International Pharmaceutical Abstracts, Internet), we failed to identify such a list. We therefore proceeded to compile our own list of these medications. The list was compiled by using *Facts and Comparisons* 4.0, available at www.factsandcomparisons.com, and the online *Physicians' Desk Reference*, available at www.pdr.net, using the Advanced Search functions. These databases are restricted databases, but are available at the IDIC. The search was performed using the term "light" and was then repeated with the term "moisture." The search yielded an extensive list of drug monographs, with each monograph bearing at least one of the search terms. Each monograph was then analyzed to determine whether it states that the medication necessitates protection from light or moisture, or is light- or moisture-sensitive. The compilation consists of 300 medications, of which 233 are light-sensitive and 146 are moisture-sensitive.

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Click here to download a .pdf document with a complete, printable list. [click here for drug list and sensitives \[http://lightandmoisture.pdf\]](http://lightandmoisture.pdf)

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Generic Name	Brand Name	Light Sensitive	Moisture Sensitive
Acarbose	Precose		*
Acebutolol HCl	Sectral	*	
Acetaminophen + codeine phosphate	Tylenol with codeine	*	
Acetaminophen + hydrocodone bitartrate	Vicodin, Zydome	*	
Acetazolamide	Diamox Sequels	*	
Acitretin	Soriatane	*	
Acyclovir	Zovirax		*
Aldronate sodium + cholecalciferol	Fosamax plus D	*	*
Alfuzosin HCl	Uroxatral	*	*
Aliskiren	Tekturna		*
Allopurinol	Zyloprim, Alopurin	*	
Alosetron	Lotronex	*	*
Alprazolam	Xanax		*
Amantadine hydrochloride	Symmetrel		*
Amiloride hydrochloride	Midamor		*
Amiloride/hydrochlorothiazide	Moduretic	*	*
Aminoglutethimide	Cytadren	*	
Amiodarone	Cordarone, Pacerone	*	
Amitriptyline	Elavil	*	
Amlodipine	Norvasc, Amvaz	*	
Amlodipine and benazepril hydrochloride	Lotrel	*	
Amlodipine and valsartan	Exforge		*
Amphetamine and dextroamphetamine salts	Adderall XR	*	
Anagrelide HCl	Agrylin	*	
Aspirin and dipyridamole	Aggrenox		*
Atenolol	Tenormin	*	
Atropine sulfate, hyoscymine hydrobromide, phenobarbital, scopolamine hydrobromide	Donnatal	*	*
Auranofin	Ridaura	*	
Azathioprine	Azasan	*	*
Benzephrine hydrochloride	Lotensin		*
Benazepril hydrochloride and hydrochlorothiazide	Lotensin HCT	*	*
Benzonatate	Tessalon	*	*
Bexarotene	Targretin	*	
Biperiden	Akineton	*	

Generic Name	Brand Name	Light Sensitive	Moisture Sensitive
Biphosphonate combination	, Fosamax Plus D	*	*
Bisoprolol fumarate	Zebeta		*
Bromocriptine mesylate	Parlodel	*	
Bumetanide	Bumex	*	
Bupropion hydrochloride	Wellbutrin	*	*
Buspirone	Buspar	*	
Calcitriol	Rocaltrol	*	
Calcium lactate	Cal-Lac		*
Captopril	Capoten		*
Captopril and hydrochlorothiazide	Capozide		*
Carbamazepine	Epitol, Tegretol	*	*
Carbamazepine extended-release	Carbatrol, Equetro	*	*
Carbinoxamine	Palgic, Histex CT	*	
Carvedilol	Coreg	*	*
Cefditoren pivoxil	Spectracef	*	*
Cefpodoxime	Vantin		*
Chlordiazepoxide	Librium	*	
Chloroquine phosphate	Aralen Phosphate	*	*
Chlorpromazine	Thorazine	*	
Chlorzoxazone	Paraflex, Remular-S, Parafon Forte DSC	*	
Cimetidine	Tagamet	*	
Clarithromycin	Biaxin	*	
Clomiphene Citrate	Clomid, Milophene, Serophene	*	*
Clomipramine hydrochloride	Anafranil		*
Clonazepam	Klonopin		*
Clonidine	Catapres	*	
Clonidine hydrochloride and Chlorthalidone	Clorpres		*
Clorazepate dipotassium	Tranxene	*	*
Clozapine	Clozaril, FazaClo		*
Codeine phosphate and codeine sulfate	Codeine		*
Colesulodin hydrochloride	WelChol		*
Cortisone	Cortisone	*	*
Cyclizine	Bonine, Marezine	*	
Cyclobenzaprine hydrochloride	Flexeril, Fexmid, Amrix	*	
Cysteamine bitartrate	Cystagon	*	*